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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,616

09/30/2003

Mina Chow

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08/13/2010

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EXAMINER

GRAY, PHILLIP A

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/676,616	Applicant(s) CHOW ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 115-122, 127, 128, 132 and 133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28, 115-122, 127, 128, 132 and 133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 12/1/2009. Currently amended claims 1-28, 115-122, 127, 128, 132, 133 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 12/1/2009 have been fully considered but they are not persuasive. Applicant argue that HAM does not disclose "...said tendon being able to deflect said catheter distal section when being pulled on without modifying a length of the catheter shaft" (as in clam 1 for example).

It is examiners position that Ham tendon deflects the catheter distal section however it does not modify the **entire** length of the **catheter shaft**. The "catheter shaft" in claim 1 is has both "a catheter proximal section" and a "catheter distal section". It is examiners position that the tendon of Ham does not modify the catheter proximal section and only portions of the catheter distal section. Therefore the tendon when pulled does not modify "**a length** of the **catheter shaft**". It is recommended that applicant amend the claims to specify either the "entire" length of the catheter shaft or the entire length of the distal section, if that is where the applicant wishes to distinguish over the prior art Ham.

Currently, the elements disclosed in HAM ,the prior art of record, and any obvious modifications thereof, are fully capable of satisfying all structural, functional,

spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 102 (2nd time)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ham et al. (U.S. Patent Number 5,456,667) herein after HAM. Ham discloses a deflectable catheter assembly (see figure 1) with a catheter shaft (internal compartment of 26 or 11) with a proximal section (bottom) and distal (top), a tendon (13) disposed within a first lumen (internal area of 17) which is approximately centrally located at the proximal section (note lumen position is central as it approaches near 44) and at the distal end the lumen is off center (note lumen position is off center as it approaches near top area and numeral 17), and the tendon deflects the catheter distal section, and a Catheter handle (40) coupled to the shaft, including a first control mechanism (such as 38/39/41 or 43).

Concerning the claim language of “said catheter proximal section having a length greater than that of the catheter distal section” it is examiners position that Ham does

have a proximal section length greater than the distal section length. The claim fails to specify where the proximal and distal sections start and end. The only requirements are that the distal is more flexible than the proximal. For example one analysis of Ham could be the first 4 inches of the proximal end of the Ham device is the "proximal section" and the last inch of the Ham device is the "distal section". It is recommended that applicant specify in greater detail what constitutes the exact metes and bounds of the "proximal" and "distal" catheter sections (i.e. where do they start and end and do they transition directly into the other or is there a transition region, ect.).

Claim Rejections - 35 USC § 103 (2nd time)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Ham.

Webster discloses the claimed invention except for the lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end. Ham teaches that it is known to use the lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end as set forth in paragraphs at column 5 lines 9 through 66 to provide an efficient and centrally located means to control the device (at the handle) while deflecting or moving the catheter tip in a given direction (near distal end). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Webster with the lumen in the catheter shaft which is centrally located in the proximal end and off center in the distal end as taught by Ham, since such a modification would provide the system with preferred lumen configuration for providing an efficient and centrally located means to control the device (at the handle) while deflecting or moving the catheter tip in a given direction (near distal end).

WEBSTER discloses a deflectable catheter assembly comprising: a catheter shaft (interior of element 91); a tendon (31) disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section (as in figure 8 for example) and said first lumen located off-center of said catheter shaft at said catheter distal section (as in figure 6A and 6b), said tendon being able to deflect said catheter distal section when being pulled on (as in

figures 1 and 7); and a catheter handle (14) coupled to said catheter shaft, said catheter handle including a first control mechanism (63 for example) to control said tendon, and slip bands (33). Webster also comprises a needle (not shown but inherent, see paragraphs beginning at column 3, line 16), or a plurality of needles, disposed within a lumen of said catheter shaft (not shown but in fifth lumen and an inherent feature of Webster, also concerning the limitations of claims 10-11).

Concerning claims 5 and 6, Webster further comprises, an axial spine (91 or 92) disposed around and over a first section of said tendon, said first section being substantially aligned with said catheter proximal section, said axial spine to resist axial compression along said catheter proximal section (See figure 11), and a flexible tendon sheath (95) coupling to said axial spine, said flexible tendon sheath extending a second section of said tendon and said second section being substantially aligned with said catheter distal section (see figures 1-14)

Concerning claim 8 and 9, Webster discloses a tip electrode (29) located at the tip of said catheter distal section and coupled to a conductive lead that extends out of said catheter shaft and at least one additional electrode (28). Webster discloses a deflectable catheter fully capable of all flexibility requirements in claims 16-17 (see figure 7). Further, Webster discloses a pre-shaped guide sheath (92, 91) disposed around said catheter shaft that is fully capable of satisfying all functional, structural, and operational limits of the claims as written.

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Ham in further view of Edwards et al. (U.S. Patent Number 6,254,598).

Webster discloses the claimed invention except is silent as to the medical device comprising a needle or a plurality of needles with at least one inflatable balloon coupling to said plurality of needles (and with a divergent angle), tube mechanism with needle stop disposed within a lumen of a catheter shaft being extendable from and retractable into the catheter distal section and a control in the catheter handle. Edwards teaches that it is known to use the needles/balloon mechanism (figure 8) as set forth in abstract and specifically columns 5-12 to provide a unique and direct medical treatment operation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Webster with the needles/balloon mechanism as taught by Edwards, since such a modification would provide the catheter with the needles/balloon mechanism for providing a unique and direct medical treatment operation.

Claims 115-122, 127-128, 132, and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of Ham in further view of Edwards and in further view of Balbierz (U.S. Patent Number 6,770,070).

Webster in view of Ham in further view of Edwards discloses the claimed invention except for the using and coupling pressure sensors to a needle. Balbierz teaches that it is known to use and coupling pressure sensors to a needle as set forth in paragraphs beginning at column 12, line 39 to provide a specific diagnostic feedback

mechanism to the catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Webster in view of Ham in further view of Edwards with using and coupling pressure sensors to a needle as taught by Balbierz, since such a modification would provide the catheter with using and coupling pressure sensors to a needle for providing a specific diagnostic feedback mechanism to the catheter. Balbierz further discloses using and coupling pressure sensors to a needle that would be fully capable of satisfying all structural, functional, and operational claim limitations.

Concerning claims 132 and 133, Webster in view of Ham in further view of Edwards discloses the claimed invention except is silent about the needle made of a polymer material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle of a polymer material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767